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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,568	07/30/2001	Wataru Morikawa	20-48418	2810
2292 7590 05/21/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			NOTIFICATION DATE 05/21/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Office Action Summary**

Application No.

09/806,568

Applicant(s)

MORIKAWA ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 11, 15, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 11, 15, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/19/2002; 04/10/2003</u> . | 6) <input type="checkbox"/> Other: ____.  |

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### DETAILED ACTION

1. Claims 1, 3, 11, 15, 17 and 18 are pending.

Claims 1, 3, 11, 15, 17 and 18 are examined on the merits.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 11, 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Faust et al. (Proceedings of the National Academy of Sciences of USA 82: 4910-4914, August 1985/ IDS reference submitted December 19, 2002), as evidenced by Morikawa et al. (Proc. Natl. Acad. Sci. USA 82: 4910-4914, August 1985/ IDS reference submitted October 3, 2006). Faust discloses a protein, which is an isolated aspartic enzyme obtained from human hepatoma G2 having a N-terminal amino acid sequence, LVR IPLHKFT (SEQ ID NO: 1), see page 4910, abstract and Figure 4 on page 4912, amino acid sequences –44 to –35. “The molecular weight for the mature unglycosylated protein calculated from the predicted sequence is 37,8000”, which is within the range of about 45kDa, see page 4913, column 1, last sentence. This same protein as evidenced by Morikawa is secreted by human prostate carcinoma

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cells, PC-3 and able to generate angiostatic peptides comprising kringle domains 1-4 of plasminogen, see page 38913, column 1, 1<sup>st</sup> full paragraph; page 38914 with particularity column 2, Identification...section; Figure 4 caption on page 38916. The disclosed protein's activity was inhibited by pepstatin A, an aspartic proteinase and generates angiostatic peptides of plasminogen mostly strongly at pH 4.0, see Morikawa abstract and page bridging paragraph of page 38914. The disclosed protein of Faust as evidenced by Morikawa is able to exert an antiproliferative effect associated with inhibiting tumor angiogenesis thereby a medicament for treating solid cancer, see the abstract of Morikawa and page 38919 of Morikawa, 2<sup>nd</sup> column. Given the disclosed protein has all the attributes claimed it is regarded as a plasminogen angiostatin converting enzyme a pH 4 (PACE4) by the Examiner.

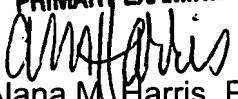
4. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**

  
Alana M. Harris, Ph.D.  
14 May 2007